

REMARKS

1. The application was filed with 61 claims, of which Claims 27-61 have been withdrawn. Claims 1-26 remain pending in the application. Claims 1, 2, 4, 6, 7, 13 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. 6,960,179 to Victor Gura (“Gura”). Claim 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable in view of Gura and Bene, U.S. Pat. No. 5,470,483. Claims 5 and 8-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable in view of Gura and U.S. Pat. No. 7,241,272, to Karoor. Claims 11 and 12 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gura in view of U.S. Pat. Appl. Publ. 2001/0041892 to Burbank. Claim 17 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Gura in view of U.S. Pat. No. 4,950,259 to Geary. Claims 18 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gura in view of U.S. Pat. No. 3,827,975 to Bizot. Claim 20 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Gura in view of U.S. Pat. No. 4,229,299 to Savitz. Claims 15, 24 and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gura in view of U.S. Pat. No. 5,522,998 to Polaschegg. Claims 16, 21-23 and 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gura in view of Burbank, U.S. Pat. No. 6,579,253.

2. Claims 1, 2, 4, 6, 7, 13 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. 6,960,179 to Victor Gura (“Gura”). Applicants traverse the rejections. Gura does not teach at least Claim 1 of the present application. Claim 1 recites, for example, “the second fluid loop being closed except for the transfer of the selected component via the membrane device.” The rejection cites Gura, second fluid loop, Fig. 3 (150, 200) and Fig. 4 (37, 200, 305). Gura also teaches, however, in Fig. 3 and in col. 6, lines 12-18, that the dialysate inlet tube 360 has a second inlet or side port (300 in Fig. 3, 380 in the text), for the infusion of additives, which can be forced into the blood via a series of pumps (270, 280, 290, 300), the infusion rate controlled electronically by the microprocessor in electronic control section 60.

Thus, Gura’s second loop is not closed as recited in the claim, “except for the transfer of the selected component via the membrane device,” i.e., the uremic toxin. Gura teaches additives in this passage that transfer from the dialysate into the blood, not from the patient fluid loop to the second fluid loop. Gura does not teach a second fluid loop as claimed, because the cited loop

is not closed. The Office Action therefore fails to make out a prima facie rejection. Claim 1 and all claims depending from Claim 1, Claims 2-26 are therefore allowable.

Claim 4 is also not taught or even suggested in Gura. Claim 4 recites that the patient loop is closed except for the transfer of the selected component via the membrane device. As seen in Figs. 3-4, Gura's patient (blood) loop includes blood inlet 33 and return 37. Gura's loop also includes a side port 180 for an anticoagulant pump 190, and thus is not closed. In addition, the return loop 37 includes an additional side port 200 for infusion additives from four infusion pumps 270, 280, 290 and 300, and is also not closed. Gura's patient loop thus includes five additional inputs and is not closed, as claimed. Claim 4 is allowable for this additional reason.

3. In addition, many of the other claims depending from Claim 1 are also allowable in their own right, because the references do not teach or suggest, i.e., consider, all the limitations of the claims. M.P.E.P. 2143.03. For example, Claims 5 and 8-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable in view of Gura and U.S. Pat. No. 7,241,272, to Karoor. Applicants traverse the rejections of Claims 5 and 8-10.

Claim 5 recites that the membrane device includes a nanofilter. The office action cites Karoor, Fig. 1, filter 20, as teaching this limitation, stating that the filter of Karoor performs the identical function as the claimed nanofilter, of allowing urea to pass. Karoor does not mention a nanofilter, describing filter 20 only as a "dialyzer." Col. 6, lines 10-49. The rejection does not even contend that Karoor teaches the claimed nanofilter. In contrast, the application describes the claimed filter, as seen in Fig. 8, as operating on the dialysate and allowing most of the electrolytes to return to the solution bag 18, which separates the urea and a small amount of sodium. Application, para. [0195, 0196]. This does not limit the application of the filter in the claimed system, but does verify that a nanofilter indeed operates on nanoscale sizes of moieties. Karoor does not teach or suggest this limitation of Claim 5, which is therefore allowable.

Karoor is also cited as teaching or suggesting Claims 8-10, the office action citing gas separator 32. Gura teaches a wearable continuous renal replacement therapy device, which, as seen in Gura Fig. 1, is lightweight, compact and portable. Karoor teaches a gas separation device or chemical cartridge 32, for removing gas from the flow of dialysate. Karoor also teaches, per col. 6, line 5, to col. 7, line 4, a system with a disposable set including a pump cassette, a dialyser, and solution concentrate, the system including two loops with a variety of components,

such as the gas cartridge 32. There is no teaching whatever that Karoor's system is wearable and portable – indeed, the use of a system with a disposable cassette, a chemical cartridge, and a vent appears to argue against the combination of Karoor with Gura, because the combination will definitely not be wearable, contrary to what Gura teaches.

Accordingly, Karoor cannot be combined with Gura, because the combination would change the principle of operation of Gura, a wearable, portable device. M.P.E.P. 2143.01 (VI). The office action thus fails to make out a *prima facie* case of obviousness, and Claims 8-10 are allowable for the additional reason that the references cannot be combined. The Examiner is thus respectfully requested to withdraw the rejections of Claims 5 and 8-10.

4. Claims 11 and 12 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gura in view of U.S. Pat. Appl. Publ. 2001/0041892 to Burbank. Claim 17 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Gura in view of U.S. Pat. No. 4,950,259 to Geary. Claim 20 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Gura in view of U.S. Pat. No. 4,229,299 to Savitz. Claims 11, 12, and 17 are allowable because they depend from allowable Claim 1. Claim 20 has been amended to better define the invention. Support for the amendment is found at least in the specification as filed, paragraph [0143].

5. Claims 18 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gura in view of U.S. Pat. No. 3,827,975 to Bizot. Claim 18 recites an inline heater, while Claim 19 recites that the inline fluid heater of Claim 18 includes a radiant heater and a plate heater. The rejection cites Bizot, while admitting that Bizot does not teach the limitations of Claim 19. Office Action, pp. 8-9, numbered paragraph 27, stating that even though the reference does not teach these limitations, that other heaters are equivalent for the desired purpose and that the substitution would have been obvious.

Applicants traverse the rejection. In order to make out a *prima facie* case of obviousness, the references must at least consider all the limitations of the claims. Bizot does not teach a heater, but rather a heat exchanger 12, with hot water lines coming into and out of the heat exchanger. The heat exchanger could be a hot-water heat exchanger, connected, for example, to a household or institutional hot-water heater, rather than a local heater as claimed. Gura does not teach a heater for the simple reason that Gura teaches a wearable, portable system. It is not

possible to combine Bizot's tethered heat exchanger with Gura's wearable portable system, because the user of Gura's portable system would have to remain tied to the in-out lines fluid lines, as shown in Bizot's figure. Thus, the combination would change the principle of operation of Gura, a wearable, portable device. M.P.E.P. 2143.01 (VI).

Accordingly, the references do not consider all the limitations of Claims 18 and 19, and the combination would change the principle of operation of Gura. The Examiner is thus respectfully requested to withdraw the rejections of Claims 18-19.

6. Claims 15, 24 and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gura in view of U.S. Pat. No. 5,522,998 to Polaschegg. As noted above in the discussion for Claim 1, all the dependent claims of the application are allowable because they depend from allowable Claim 1. In addition, at least Claim 25 is separately allowable because Polaschegg fails to teach or suggest the limitations of Claim 25, which recites "a fluid concentrate container in fluid communication with at least one of the patient and second fluid loops."

The rejection cites Polaschegg, Fig. 1 and container 42, as teaching the fluid concentrate container, which is described as "a dialysis fluid source" connected to pumps and valves. Col. 5, lines 9-12. Thus, container 42 is a container of dialysis fluid, such as a bag or container of dialysis fluid. Claim 25 of the present application, however, recites a "fluid concentrate container," (emphasis added) which is described as a container to replenish electrolytes for the patient, such as bicarbonate or the like. Application, para. [0123] to [0125]. Polaschegg teaches only a standard dialysate container, not a fluid concentrate container as claimed. Accordingly, Claims 15 and 24 are allowable because they depend from allowable Claim 1, and at least Claim 25 is additionally allowable because Polaschegg fails to teach concentrate or a concentrate container. The Examiner is respectfully requested to withdraw the rejections of at least Claims 15, 24 and 25.

7. Claims 16, 21-23 and 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gura in view of Burbank, U.S. Pat. No. 6,579,253. Claims 16 and 26 are allowable at least because they depend from allowable Claim 1. Claims 21-23 are also allowable, because Burbank does not teach or suggest a fluid volume sensor. Burbank at most teaches a fluid flow rate detector 182, col. 11, line 48. A fluid flow rate detector may simply detect the presence of

flow, e.g., a thermocouple that is heated or cooled because it is in contact with flowing liquid. A flow rate detector does not inherently teach or suggest a fluid volume sensor as recited in Claims 21-23. Accordingly, Gura and Burbank do not teach or suggest at least Claims 21-23. Claims 16, 21-23, and 26 are additionally allowable because they depend from allowable Claim 1.

8. For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same. Applicants believe no fees are due. However, if any fees are due and payable, except for the issue fee, the Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

Respectfully submitted,
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